ADVERSE EVENTS

Throughout the course of the study, all adverse events will be monitored and reported on an adverse event case report form, including seriousness, severity, action taken and relationship to study drug. If adverse events occur, the first concern will be the safety of the study participants.

DEFINITIONS

Adverse event (AE)

Any untoward medical occurrence in a patient or clinical investigation patient administered a pharmaceutical product and that does not necessarily have a casual relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
Note: Worsening of the disease/condition being evaluated, outside of normally expected variations, which occurs during the study is considered an adverse event. Lack of efficacy of the study treatment is not considered an adverse event.

Serious adverse event (SAE)

An adverse event occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

SEVERITY

A clinical determination of the intensity of an adverse event. The severity assessment for a clinical adverse event should be completed using the following definitions as guidelines:

Mild:	Awareness of sign or symptom, but easily tolerated.
Moderate:	Discomfort enough to cause interference with usual activity.
Severe:	Incapacitating with inability to work or do usual activity.
Not applicable:	In some cases, an adverse event may be an “all or nothing” finding, which cannot be graded.

RELATIONSHIP TO STUDY DRUG

A determination of the relationship (if any) between an adverse event and the study drug. The relationship should be determined using the following definitions as guidelines:

Unrelated: Either:

1) The adverse event is clearly not related to the study drug and is clearly related to an underlying disease, environmental or toxic factors, or other drug or therapy.

   or

2) The adverse event does not follow a reasonable temporal sequence after study drug administration (e.g., too soon or too long after study drug was taken or study drug was not taken) and is plausibly related to an underlying disease, environmental or toxic factors, or other drug or therapy.

   Possible: The adverse event occurred in a reasonable time after study drug administration but could be related to an underlying disease, environmental or toxic factors, or other drug or therapy.

   Probable: The adverse event occurred in a reasonable time after study drug administration and is unlikely to be related to an underlying disease, environmental or toxic factors, or other drug or therapy. The event may respond to stopping the study drug.

   Definite: The adverse event occurred in a reasonable time after study drug administration and is not explained by an underlying disease, environmental or toxic factors, or other drug or therapy. The event should respond to stopping the study drug and recur on rechallenge (were these to take place).

PROCEDURES FOR REPORTING A SERIOUS ADVERSE EVENT

Any serious adverse event occurring during the study period, should be immediately reported to A QEI representative listed on the QEI personnel page and recorded on the appropriate case report forms. All patients with a serious adverse event must be followed up and the outcomes reported. The investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).

In the event of a serious adverse event, the investigator must:

1. Notify QEI immediately. For Emergency Phone Numbers see front of the protocol and Personnel page.

2. Obtain and maintain in his/her files all pertinent medical records, information, and medical judgments form colleagues who assisted in the treatment and follow-up of the patient.

3. Provide QEI with a completed, written case history (Adverse Event Report Form) which includes a statement as to whether the event was or was not related to the us of the investigational drug.

4. Promptly inform the QEI of the serious adverse event.

ADVERSE REACTION TO OPHTHALMIC DRUGS REPORTING FORM

The optometrist shall report to the Board, on the form provided by the Board, within 10 working days of the occurrence of any adverse reaction resulting from administration of any pharmaceutical agent or from the removal of a superficial foreign body from the eye. This information is not subject to public disclosure pursuant to the provisions of the Annotated Code of Maryland, State Government Section 10 - 617 (h).

Optometrist's Name _____License Number _____

Optometrist's Address _____

City_____ State _____ Zip Code _____

Date of Occurrence: _____

Initial Diagnosis/Presenting Problem: _____

_____

Agents Administered and Method of Administration: _____
_____
_____
_____

Adverse Reaction: (circle one)

Painful Eyes	Wheezing	Cessation of Respiration
Wheals	Pruritis (itching)	Skin Rash of Periorbital
Fainting	Chest Pain	tissue
Nausea	Uriticarial Lesions (hives)	Clinically significant
Vomiting	Confusion	change in heart rate

Other_____

Subsequent Action Taken: _____
_____

(Attach additional sheets if needed)